DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 10, 2014

Pivotal Health Solutions
Attn: Aaron Tvedt
Quality Manager
724 Oakwood Road
Watertown, SD 57201

Re: K131983
Trade Name: iTrac c2i Cervical Traction System
Regulation Number: 21 CFR 890.5900
Regulation Name: Powered traction equipment
Regulatory Class: Class II
Product Code: ITH, ILZ, IRS
Dated: September 2, 2014
Received: September 8, 2014

Dear Mr. Tvedt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131983

Device Name
iTrac c2i Cervical Traction System

Indications for Use *(Describe)*
The iTrac c2i cervical traction system is intended for use as a conservative treatment alternative in patients presenting with cervicogenic pain symptoms of mechanical origin related to reduced cervical lordosis/extension and altered posture. It temporarily positions the cervical spine into an extension posture of varying degrees, as determined by a clinician. This device is for prescription use only and is not provided in a sterile condition.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.09.10 16:56:32 -04'00'

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Section 5

510(k) Summary

This 510(k) Summary has been prepared in accordance the requirements of 21 CFR 807.92.

510(k) Summary

1. **Submitter's Identification:**

Aaron Tvedt (Official Correspondent)
Pivotal Health Solutions, Inc.
724 Oakwood Road
Watertown SD, 57201
Phone: 605-753-0110
Fax: 605-882-8398

Establishment Registration Number: 3007278668

Date Prepared: September 3, 2014

2. **Name of the Device:**

Trade Name: iTrac c2i Cervical Traction System
Common Name: Power Traction Equipment
Regulation Number: 21 CFR, Section 890.5900
Regulation Name: Powered Traction Equipment
Regulatory Class: II
Product Code: ITH

3. **Name of the 510(k) Cleared Device (Predicate Device):**
CTBox Cervical/Lumbar Traction System (K063353)
Common Name: Power Traction Equipment
Regulation Number: 21 CFR, Section 890.5900
Regulation Name: Powered Traction Equipment
Regulatory Class: II
Product Code: ITH (Primary), ILZ, IRS (Secondary codes)

4. **Device Description**:

The iTrac™ c2i cervical traction system is intended for use as a conservative treatment alternative in patients presenting with cervicogenic pain symptoms of mechanical origin related to reduced cervical lordosis/extension and altered posture. It temporarily positions the cervical spine into an extension posture of varying degrees, as determined by a clinician. This device is for prescription use only and is not provided in a sterile condition.

Operational software controls the exertion and release of the pulling forces, operation cycle, and treatment times prescribed by the physician. The iTrac's operational

components consist of software, an air compressor, three pneumatic cylinders, two electro-pneumatic regulators, a traction line and pulley system, head halter, fulcrum strap, magnetic safety release, backup flow controls, and mechanical pressure relief valves.

All accessories necessary to provide the traction to the patient are included with the device making it a ready to use traction device. A head halter captures the patient's chin during treatment and is connected to an adjustable overhead traction bar that can be manually adjusted by the doctor to the doctor-prescribed traction angle. A fulcrum strap rests on the back of the patient's neck and may be used to provide an additional anterior force. During setup, an electric lift column allows the fulcrum/traction section to be raised or lowered by the doctor to the height doctor prescribed for each patient.

For each treatment session the Doctor commands the software to implement a specific treatment time, traction force, and fulcrum force. Utilizing a piecewise linear function calculation the software generates an output signal causing the electro-pneumatic pressure controllers to adjust pressure, delivering the doctor prescribed forces to the fulcrum and traction cylinders. For safety, limits are hard coded in the software to prevent traction and fulcrum forces from exceeding the allowable limits. The software is loaded on a standard personal computer which interfaces with the device via a standard network connection; this standard connection is limited to connection only with the iTrac.

A Patient Stop Switch provides additional protection to the patient by operating independent of software to relieve all forces when pressed. When activated, the patient stop switch triggers a relay which, in turn, triggers a solenoid-controlled pneumatic valve causing a quick stop and venting of all pneumatic pressure to the cylinders. This action immediately relieves the patient of traction forces and sends a discrete output from the relay to the I/O Module, placing the treatment session into 'Pause' within the software. As an added safety measure the software requires the patient stop switch to be pressed before the start of each treatment during the treatment start protocol to ensure its functionality.

5. Intended Use Statement:

The iTrac™ c2i cervical traction system is intended for use as a conservative treatment alternative in patients presenting with cervicogenic pain symptoms of mechanical origin related to reduced cervical lordosis/extension and altered posture. It temporarily positions the cervical spine into an extension posture of varying degrees, as determined by a clinician. This device is for prescription use only and is not provided in a sterile condition.

6. **Technological Characteristics**

The iTrac is substantially equivalent to the CTBox Cervical/Lumbar Traction System (predicate), without any significant difference in main technological and operational features. Both devices are intended for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.

Table 5A provides a summary of the technological characteristics of the iTrac c2i in comparison to the CTBox Cervical/Lumbar Traction System.

Table 5A: Summary of Technological Characteristics of iTrac c2i compared to CTBox Cervical/Lumbar Traction System

	iTrac™ c2i cervical Traction System	CTBox Cervical/Lumbar Traction System	Similarities/ Differences	Analysis
Intended Use	The iTrac™ c2i cervical traction system is intended for use as a conservative treatment alternative in patients presenting with cervicogenic pain symptoms of mechanical origin related to reduced cervical lordosis/extension and altered posture. It temporarily positions the cervical spine into an extension posture of varying degrees, as determined by a clinician. This device is for prescription use only and is not provided in a sterile condition.	The "CT BoxTM" cervical/lumbar traction system is intended for use as a conservative treatment alternative in patients presenting with cervicogenic /lumbogenic pain symptoms of mechanical origin related to reduced cervical or lumbar lordosis/extension and altered posture. It temporarily positions the cervical or lumbar spine into an extension posture of varying degrees, as determined by a clinician. This device is for prescription use only and is not provided in a sterile condition..	Same (except for the CT Box may be used in patients presenting with lumbogenic pain symptoms).	
Treatment Area	Cervical	Cervical or Lumbar	Same (Cervical)	The iTrac's intended treatment area is cervical only which allows force limits to be set specifically and appropriately for this treatment area, providing additional protection to the patient.

Table 5A: Summary of Technological Characteristics of iTrac c2i compared to CTBox Cervical/Lumbar Traction System				
	iTrac™ c2i cervical Traction System	**CTBox Cervical/Lumbar Traction System**	**Similarities/ Differences**	**Analysis**
Treatment Position	Seated	Seated or Supine	Same (Seated)	The iTrac is intended for use with patients in seated position. Incorporating the chair and other accessories as part of the device assures the same level of design and manufacturing quality has been applied.
Lift Mechanism	Electromechanical	Electric	The iTrac uses a fixed chair with an electromechanical lift column to elevate the traction section to the required height for each patient.	Same as above.
Traction force	The min. and max. traction force= 0-20lbs (traction force) /0-40 lbs.(Fulcrum force)	Cervical traction: 40lbs Lumbar traction: 80 lbs	iTrac's traction force limit is within the cervical limits of the predicate device.	The iTrac's force limits are designed specifically for cervical traction therapy, which provides additional safety to the patient.

Table 5A: Summary of Technological Characteristics of iTrac c2i compared to CTBox Cervical/Lumbar Traction System				
	iTrac™ c2i cervical Traction System	**CTBox Cervical/Lumbar Traction System**	**Similarities/ Differences**	**Analysis**
System Control	Computer-controlled traction system with operational software residing on computer	None.	. Difference - iTrac software resides on a computer. The iTrac uses operational software to control traction force, speed, and time	The iTrac software residing on a computer creates no additional safety and effectiveness issues.

Table 5A: Summary of Technological Characteristics of iTrac c2i compared to CTBox Cervical/Lumbar Traction System				
	iTrac™ c2i cervical Traction System	**CTBox Cervical/Lumbar Traction System**	**Similarities/ Differences**	**Analysis**
Operational Components	Air compressor and Pneumatic cylinders, software controlled pneumatic regulator, pulley assembly	Eccentric Drive Motor, pulley assembly	Same - Both operational components generate a linear force conveyed through a pulley system to provide therapeutic forces on the patient. Difference - iTrac uses compressed air and pneumatic components to generate force. CT Box generates force via suspended weights and/or ratcheting winches, then creates a additive or delta force of 1 to 7 additional pounds by use of an eccentric drive motor. The CTBox is a metal box that houses a simple gear motor that revolves rope hook-ups that will slightly and constantly increase and decrease the transverse and/or	Both devices provide a linear force conveyed though a pulley system to provide a therapeutic pulling force on the patient's body. The iTrac utilizes compressed air to create the traction force. This creates no additional safety and effectiveness issues, and eliminates the potential for EMC safety issues by eliminate the need for the electric motor used by the predicate.
Traction Speed	Stepless, Continuous, Adjustable	Continuous and Adjustable	Same, except the iTrac provides stepless traction	The iTrac uses stepless traction, which provides for fluid motion, which provides better comfort and safety for the patient.

Table 5A: Summary of Technological Characteristics of iTrac c2i compared to CTBox Cervical/Lumbar Traction System				
	iTrac™ c2i cervical Traction System	**CTBox Cervical/Lumbar Traction System**	**Similarities/ Differences**	**Analysis**
Force display	Actual Force / Preset Force	Analog weight scale	The iTrac offers a digital force display, while the predicate does not.	The iTrac provides additional safety to the patient through accurate display of the force display.
Treatment time	5-15 min	15-20 minutes.	Treatment time limits are within the time limits of the cleared predicate	Treatment time is limited to the required time for cervical treatments, providing added protection to the patient.
Therapy Mode	Continuous	Continuous force, Intermittent traction	iTrac and cleared predicate both offer continuous therapy mode.	Intermittent mode is not required for the iTrac's Intended Use.
Safety system	Multiple protections including patient safety switch, manual release, unit stop button, compressor regulator, magnetic safety release, pressure release valve, backup flow control, feedback gauges.	Manual Release, Hand held on/off switch This provides release ONLY from the delta or additive 1 to 7 pound force – the primary force remains in effect until released by the operator.	ITrac's patient stop switch releases all forces/ the CTBox releases only the 7 pound delta force.	iTrac provides additional safety controls to protect the patient.

Table 5A: Summary of Technological Characteristics of iTrac c2i compared to CTBox Cervical/Lumbar Traction System				
	iTrac™ c2i cervical Traction System	**CTBox Cervical/Lumbar Traction System**	**Similarities/ Differences**	**Analysis**
Power supply	110-120V (60Hz) 220-240V (50Hz)	115V (60Hz)	Same	
Allowable Voltage Fluctuation	Max±10%	UNK	Different – the Allowable voltage fluctuation is not known for the predicate device.	The iTrac has been verified to have Max±10% of voltage fluctuation through NRTL testing
Casing leakage of electricity	< 100 Microamps	UNK	Different – The leakage current specification is unknown for the predicate device.	The iTrac has been verified to have <100 microamps leakage current through NRTL testing
Ground resistance	< 0.1 Ohm	UNK	Different – The ground resistance specification is unknown for the predicate device.	The iTrac has been verified to have <0.1 ohm resistance through NRTL testing

Table 5A: Summary of Technological Characteristics of iTrac c2i compared to CTBox Cervical/Lumbar Traction System				
	iTrac™ c2i cervical Traction System	**CTBox Cervical/Lumbar Traction System**	**Similarities/ Differences**	**Analysis**
Electric Classification and Type	Class I / Type B	UNK	Different – The electric classification and type specification is unknown for the predicate device.	Type BF is for devices that have conductive contact with the patient, or having medium or long term contact with the /patient. When applied parts are not conductive, Type B is the appropriate protection. The iTrac has been verified to have Class I/Type B electric classification through NRTL testing
Electrical Compliance Testing	IEC 60601-1, IEC 60601-1-2 by Accredited Test Laboratory	The motor, power cord and on-off hand held switch meets all UL safety standards	Same	
EMC Compliance Testing	IEC 60601-1-2 by Accredited Test Laboratory	The motor, power cord and on-off hand held switch meets all UL safety standards	Same	

Table 5A: Summary of Technological Characteristics of iTrac c2i compared to CTBox Cervical/Lumbar Traction System				
	iTrac™ c2i cervical Traction System	**CTBox Cervical/Lumbar Traction System**	**Similarities/ Differences**	**Analysis**
Biocompatibility	All patient contact components tested for biocompatibility to ISO 10993 standard by Accredited Test Laboratory	Use of materials which have been previously use previously cleared medical devices.	Same	
Additional components	The iTrac system includes the iTrac device and necessary accessories to function as a ready to use traction device.	The CT Box provides the motorized mechanism for cervical and lumbar traction. The CT Box may be connected to the Traction L-Frame for additional connection to accessories: Head halter, Pelvic support belt, cords, pulleys, and ratchets.,	Difference – the iTrac is a ready to use traction device.	The iTrac comes with all the required accessories to function as a ready to use traction device.

Table 5A: Summary of Technological Characteristics of iTrac c2i compared to CTBox Cervical/Lumbar Traction System

	iTrac™ c2i cervical Traction System	CTBox Cervical/Lumbar Traction System	Similarities/ Differences	Analysis
Contraindications	• Patients with pathological lesions or congenital deformities of the vertebral column that disrupt the integrity and stability of the vertebral and ligament structures. • Neoplasm, spinal tumors; both metastasis and primary. • Spina bifida or pars defect. • Rheumatoid arthritis • Spinal cord compression • Malignancy • Patients with notable posterior spurring of their cervical vertebra • Patients with spondylolisthesis Grade 2 or greater • Patients with connective tissue disease; i.e. Scleroderma • Post-surgical patients who have had spinal surgery and healing of tissue is still required. (The period of time post	1. Patients with notable posterior spurring of their cervical vertebra. 2. Patients with large posterior disc bulges or herniations. 3. Patients with cervical spinal stenosis. 4. Patients with structural disease secondary to tumor or infection. 5. Patients with cervical vascular compromise. 6. Patients with acute sprain, strain and/or inflammation of the cervical joints. 7. Patients with cervical joint instability. 8. Patients with internal spinal fixation hardware. 9. Patients with severe osteoporosis or vertebral fractures.	Similar	The iTrac provides additional contraindications for the following conditions: • Patients with pathological lesions or congenital deformities of the vertebral column that disrupt the integrity and stability of the vertebral and ligament structures. • Neoplasm, spinal tumors; both metastasis and primary. • Spina bifida or pars defect. • Rheumatoid arthritis • Spinal cord compression • Malignancy • Patients with spondylolisthesis Grade 2 or greater • Patients with connective tissue disease; i.e. Scleroderma • Post-surgical patients who have had spinal surgery and healing of tissue is still required. (The period of time post spinal surgery will very between 6

Table 5A: Summary of Technological Characteristics of iTrac c2i compared to CTBox Cervical/Lumbar Traction System				
	iTrac™ c2i cervical Traction System	**CTBox Cervical/Lumbar Traction System**	**Similarities/ Differences**	**Analysis**
	spinal surgery will very between 6 months to a year) • Pregnancy • Patients with any other conditions that may be made worse by distraction of the spine • Patients with structural disease due to tumors or infection (e.g.,osteomyelitis, spinal caries, and ankylosing spondylitis). • Patients with joint instability, hypermobility or spinal fracture. • Patients with osteoporosis. • Patients with severe cardiovascular disease, vascular compromise, aortic aneurysm or severe respiratory disease. • Patients where movement is contraindicated. • Patients with acute sprains, strains or inflammation that could be aggravated by traction.			months to a year) • Pregnancy • Patients with any other conditions that may be made worse by distraction of the spine • Stop traction if there is an increase in radiated pain to the extremities (radicular pain). • Patients with severe cardiovascular disease, vascular compromise, aortic aneurysm or severe respiratory disease. • Patients where movement is contraindicated.

Table 5A: Summary of Technological Characteristics of iTrac c2i compared to CTBox Cervical/Lumbar Traction System				
	iTrac™ c2i cervical Traction System	**CTBox Cervical/Lumbar Traction System**	**Similarities/ Differences**	**Analysis**
	• Stop traction if there is an increase in radiated pain to the extremities (radicular pain). • Patients with large posterior disc bulges or herniations. • Patients with cervical spinal stenosis. • Patients with cervical vascular compromise. • Patients with acute sprain, strain and/or inflammation of the cervical joints. • Patients with interal spinal fixation hardware.			

7. Performance and Testing Summary

Angle and force testing demonstrate the iTrac device specifications were met and traction forces were the same as the predicate device. The design and testing of the iTrac's safety features, which include software controls, hard-coded force limits, pressure relief valves, back-up flow controls, magnetic safety release, and patient stop switch, indicate all features met specification and demonstrate equivalent performance to the predicate.

Additionally, testing performed by accredited test laboratory to IEC standards 60601-1 and 60601-1-2 demonstrate the iTrac meets the requirements for electrical and EMC safety. Biocompatibility testing performed on the iTrac's patient contact materials by an accredited test laboratory demonstrates the materials meet the applicable requirements of ISO 10993.

8. Conclusion

The iTrac c2i has the same intended use and technological characteristics as the cleared predicate, CTBox Cervical/Lumbar Traction System. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted model maintains the same safety and effectiveness as that of the cleared device.

In other words, the iTrac c2i is substantially equivalent to the CTBox Cervical/Lumbar Traction System.